3 510(k) Summary

Name of Firm:	Synthes Spine 1302 Wrights Lane East West Chester, PA 19380
510(k) Contact:	Susan Lewandowski Spine Regulatory Affairs Specialist Telephone: 610-719-5712 Facsimile: 610-719-5102
Trade Name:	Synthes Vectra System
Common Name:	Cervical Plating Instrumentation
Device Product Code and Classification:	KWQ – 888.3060 – Spinal Intervertebral Body Fixation Orthosis Class II
Substantially Equivalent Devices:	Synthes ACCS – K033844
Device Description:	The Synthes Vectra System consists of one-level to four-level plates with cancellous and cortical fixed-angle and variable-angle screws. The plate attaches to the anterior portion of the vertebral body of the cervical spine (C2-C7). The plate is 2.5 mm thick, has bigger graft visibility windows (as compared to the predicate device), bend grooves, and fixed-angle screw DTS Guide orientation holes. The plates and screws are manufactured from Titanium Aluminum Niobium (Ti-6Al-7Nb), the same as the predicate device. The plate clip is manufactured from Elgiloy (40Co-20Cr-16Fe-15Ni-7Mo), the same as the predicate device.
Intended Use / Indications for Use:	Synthes Vectra System is intended for anterior plate and screw fixation of the cervical spine (C2-C7). Synthes Vectra System is indicated for the following: Degenerative Disc Disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), Spondylolisthesis, Trauma (i.e., fractures or dislocations) Spinal Stenosis, Tumors (primary and metastatic), Failed previous fusions, Pseudoarthrosis, Deformity (i.e., scoliosis, kyphosis, and/or lordosis)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 4 2005

Ms. Susan Lewandowski
Senior Regulatory Affairs Specialist
Synthes Spine
1302 Wrights Lane East
West Chester, PA 19380

Re: K050451
Trade/Device Name: Synthes VECTRA System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: KWQ
Dated: February 18, 2005
Received: February 22, 2005

Dear Ms. Lewandowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

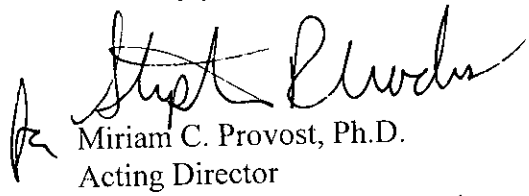
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Special 510(k) Device Modification

Indications for Use Statement

510(k) Number (if known): K050451

Device Name: Synthes VECTRA System [modification to Synthes Anterior Cervical Compression System (ACCS)]

Indications for Use: Synthes VECTRA System is intended for anterior plate and screw fixation of the cervical spine (C2-C7).

Synthes VECTRA System is indicated for the following:

- Degenerative Disc Disease (DDD) (defined as neck pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies)
- Spondylolisthesis
- Trauma (i.e., fractures or dislocations)
- Spinal Stenosis
- Tumors (primary and metastatic)
- Failed previous fusions
- Pseudoarthrosis
- Deformity (i.e., scoliosis, kyphosis, and/or lordosis)

Warning: This device is not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Prescription Use **X** (21 CFR 801 Subpart D) AND/OR Over-the-Counter Use (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K050451